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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,590	04/28/2006	William Suttle Peters	13634.4008	3167

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ORRICK, HERRINGTON & SUTCLIFFE, LLP  
IP PROSECUTION DEPARTMENT  
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IRVINE, CA 92614-2558

EXAMINER
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DINGA, ROLAND

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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03/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



<b>Office Action Summary</b>	<b>Application No.</b> 10/595,590	<b>Applicant(s)</b> PETERS, WILLIAM SUTTLE	
	<b>Examiner</b> ROLAND DINGA	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/28/2006</u> .                                              | 6) <input type="checkbox"/> Other: _____                          |



## DETAILED ACTION

### *Claim Objections*

1. Claim 20 is objected to because of the following informalities: Claim 20 recites a method step which suppose to be a device step. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Buaayu et al (JP 10-328297)(Applicant's prior art).

With respect to **claim 1**, Buaayu et al discloses a heart function assistive device 1f (see abstract). The device is adapted to be positioned about the aorta (50) of a patient for externally engaging (see abstract). The device (1) including a balloon (10) to the exterior of an aorta (12) (see abstract).

4. **Claims 1-6, 12, 15-17** are rejected under 35 U.S.C. 102(b) as being anticipated by William Suttle Peters et al (WO02/24255 A1) (Applicant's prior art). Herein Peters.

With respect to **claim 1**, Peters discloses an implantable device 10 for assisting the functioning of the patient heart (see abstract, lines 1-2). The



device is adapted to be positioned about the aorta 12 of a patient for externally engaging (see abstract, lines 3-4; page3, lines 7-8). The implantable device 10 including an inflatable balloon to the exterior of an aorta 12 (page 4, lines 28-30).

With respect to **claim 2**, Peters discloses that the balloon attached to the aorta ( “arterial vessel” ), page 4, lines 28-30.

With respect to **claim 3**, Peters discloses a wrap 78 (taken to be the shroud) forming a part of the heart assist device 70 and overlying the balloon is attached to the vessel to hold the balloon 72 in contact with the aorta (vessel)(page.13,lines 1-16).

With respect to **claim 4**, Peters discloses a heart assist device 10 which is retained adjacent the aorta 12 by a substantial inelastic sheath 18 (inelastic sheath is taken to be the shroud) placed around the cuff 14 and held in place by having the ends of the sheath sutured together by sutures. (page 11,lines11-13).

With respect to **claim 5 and 6**, Peters discloses attaching the wrap (“shroud “) of the heart assist device to an arterial vessel with the associated inflatable balloon or chamber secured beneath the shroud and adjacent the vessel (page 5, lines 13-18; page 6, lines 14-28; page 13, lines6-16).

Regarding **claim 11**, Peters discloses an inflatable compressing means (taken to be the balloon) adapted to be positioned about the aorta of a



patient for externally engaging and compressing the aorta (page 3, lines 7-8)

With respect to **claim 12**, Peters discloses attaching the balloon of the heart assist device to an arterial vessel with an associated shroud or wrap secured over the balloon and onto the aorta (vessel) (page 4, lines 28-30).

With respect to **claim 15**, Peters discloses introducing and withdrawing a fluid into and from the balloon in counter pulsation with the arterial vessel (page 5, lines 25-30; page 8, lines 4-10).

With respect to **claim 16**, Peters discloses a heart assist device 10 including a wrap and an inflatable balloon 14, wherein the wrap has a larger peripheral extent than that of the balloon, and at least some of the periphery of the wrap is adapted for direct attachment to the arterial vessel (see fig. 1, 3, 8 & 9).

With respect to **claim 17**, the shroud (wrap) in (fig. 8) periphery is inherently adapted for suturing to the vessel.

5. Claim **22** is rejected under 35 U.S.C. 102(b) as being anticipated by William Suttle Peters et al (WO00/76288 A2) (Applicant's prior art). Herein Peters.

Regarding **claim 22**, Peters discloses a method of heart assistance (see abstract); gluing the compression means (the compression means is taken to be the "the inflatable balloon") of a heart assist device to a wall of an



arterial vessel (page.8, lines 30-33) and inflating the balloon to cause inward displacement of the wall in the region that is adjacent the balloon (page 7, lines 10-11& lines 14-17).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims **7-10,13-14,18-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over William Suttle Peters et al (WO2002/24255 A1) as applied to **claims 1 or 16** above. Herein Peters.

With respect to **claim 7**, it would have been obvious to one of ordinary skill in the art to use non-absorbable sutures, because it would enable a permanent attachment of the assistive device on the artery.

With respect to **claim 8, 9, 10**, Peters discloses a wrap (taken to be the shroud) but failed to disclose gluing, stapling, clipping the shroud to the vessel. It is well within the purview of the art to choose glue, staple(s), or clip(s) for attaching. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of these attachment means for the process of Peters because these are well known methods of attaching or holding the device in position relative to the aorta.



With respect to **claim 13**, Peters failed to disclose gluing the balloon to the vessel. However, such would have been obvious to one of ordinary skill in the art to glue the balloon to the vessel in Peters' method in order to permanently attach the balloon to the vessel so that the balloon can compress and decompress the aorta (vessel).

With respect to **claim 14**, Peters failed to disclose that directly attaching the balloon of the heart assist device to an arterial vessel with an associated fibrin. However, it is well known in the art to use fibrin as a glue. Thus, it would have been obvious to one of ordinary skills in the art by the time the invention was made to use fibrin as a glue to attach the balloon of the heart assistive device to the arterial vessel in the device of Peters because it is a well known natural protein use for attachment during surgery.

Regarding **claim 18**, Peters failed to disclose that the wrap (shroud) periphery is sutured to the intercostal fascia and fascia overlying the vertebral column. However, such would have been obvious to one of ordinary skill in the art to have the shroud periphery sutured to the intercostal fascia and fascia overlying the vertebral column in the design of Peters because fascia strong connective tissues.

With respect to **claims 19-21**, Peters discloses a wrap (take to be the shroud) but failed to disclose gluing, stapling, clipping the shroud to the



vessel. It is well within the purview of choose in the art to use glue, staple or clip for attaching. It would have obvious to one of ordinary skill in the art by the time the invention was made to use either attachment means to the process of Peters because these are well known method of attaching or holding the device in position relative to the aorta.

### ***Other Prior Art Cited***

The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure.

(1) William N.Aldrich (US 6585635) teaches a heart assistive device that uses fibrin-based glues, suturing, clipping, stapling for bonding the parietal pericardium to the visceral pericardium.

### **CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROLAND DINGA whose telephone number is 571 270 3644. The examiner can normally be reached on Monday through Friday from 8:30am to 5:00pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571 272 4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RD  
02/19/2008

/Carl H. Layno/  
Supervisory Patent Examiner, Art  
Unit 3766